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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,817	11/26/1999	Mitchell S. Steiner	P-2762-US1	6736

27130 7590 07/26/2004

EITAN, PEARL, LATZER & COHEN ZEDEK LLP
10 ROCKEFELLER PLAZA, SUITE 1001
NEW YORK, NY 10020

EXAMINER	
KERR, KATHLEEN M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/449,817	STEINER ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,10-16,18-27,54-56 and 59-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,10-16,18-27,54-56,63 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *alignment*.

DETAILED ACTION

Application Status

1. In response to the previous Office action, the previous Office action on the merits (mailed on January 28, 2003), Applicants filed (a) an after-final amendment and notice of appeal on July 28, 2003, which amendment was not entered, (b) an RCE with accompanying amendment on December 29, 2003, which amendment inappropriately switched inventions for prosecution, (c) a supplemental amendment on April 15, 2004 switching back to the original invention, and (d) a second supplemental amendment on May 3, 2004 to amend the claims further.

All tolled, Claims 17, 30-36, 40, 44, 45, 47, and 57-58 have been cancelled, Claims 1, 7, 12, 13, 15, 16, 20, 21, 24, 54-56, and 59 have been amended, and Claims 61-63 have been added. Thus, Claims 1, 7, 10-16, 18-27, 54-56, and 59-63 are pending in the instant application and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 09/302,457 filed on April 29, 1999; however, the elected subject matter has priority to the filing date of the instant application that is November 26, 1999.

Applicant addresses this lack of granting priority to the pending claims, arguing that the earlier application, 09/302457, does teach the human p-Hyde claimed in the pending claims. The Examiner disagrees. While the sequence in Figure 19A is originally disclosed as a human p-Hyde gene (856 bp), it is *not* SEQ ID NO:1 (733 bp) of the instant application and claims. By inspection, the Examiner also determined that the amino acid sequence in Figure 19B (133 aa) is

only similar to SEQ ID NO:2 (186 aa) of the instant application in the first (N-terminal) 65 residues and the C-terminus is wholly different from SEQ ID NO:2.

Therefore, the Examiner maintains that the instant claims are not granted an earlier effective filing date for prosecution herein; the priority date for purposes of prior art in the instant Office action is November 26, 1999 (instant filing date).

Drawings

3. The drawings filed on July 28, 2003 have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Compliance with the Sequence Rules

4. While Applicant's filed the appropriate statement as requested previously by the Examiner, said statement was unnecessary as the Examiner located a statement of sameness and no new matter as filed by Applicants on August 14, 2001 (6 sequences). Thus, the application fully complies with the sequence rules by virtue of the sequence listing filed on August 14, 2001 containing 6 sequences.

Maintained – Objections to the Specification

5. Previous objection to the specification for containing confusing reference materials is maintained. Applicant note that the references to numbers in the specification have been corrected; this is not the case. As previously noted,

> "Throughout the application, for example on page 25, line 25, bracketed references such as "[74]" are found but do not correlate to the reference citations at the end of the application. Amendment to these references must be added to include the proper citations."

6. Previous objection to the Abstract is maintained. Applicants have amended the abstract, but said amendment has not completely obviated the previous objection. As previously noted, the Abstract is objected to for not *completely* describing the disclosed subject matter. The Examiner suggests the inclusion of both source species, ***human and*** rat, for completeness. Applicants are reminded that the Abstract must describe the entire disclosure and not just what is claimed. Correction is required.

New – Objections to the Specification

7. The specification is objected to for its reference to SEQ ID NO:7 as amended into page 83. No new sequence listing has been filed; the sequence listing filed on August 14, 2001 includes only 6 sequences. In a paper filed on December 29, 2003, a filing of a new sequence listing is mentioned in the remarks, but none was received in computer readable form or paper copy. Correction and/or clarification are required.

Withdrawn - Claim Objections

8. Previous objection to Claim 7 for having an improper Markush group is withdrawn by virtue of Applicant's amendment.

9. Previous rejection of Claims 12-17 to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicant's amendment to Claims 12 and 16 making them independent claims.

10. Previous objection to Claim 14 for having an improper format and for being inconsistent with previous claims is withdrawn by virtue of Applicant's amendment.

11. Previous rejection of Claim 59 for depending from a non-elected claim is withdrawn by virtue of Applicant's amendment to Claim 59 to depend from Claim 7., Claim 53.

New - Claim Objections

12. Claim 1 is objected to for having improper language. The phrase nucleic acid molecule **encoding for** a ...protein" (emphasis added) is improper because a nucleic acid molecule either "encodes a protein" or "codes for a protein". Correction is required.

13. Claim 7 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since the parent Claim 1 requires the nucleic acid molecule to encode a protein and DNA and RNA are the only nucleic acid molecules that encode proteins, these limitations do not further limit the scope of Claim 1.

14. Claim 26 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since prokaryotic and eukaryotic are the only options for host cells, the instant claim removes no breadth of the scope of Claim 25 which is required to further limit the parent claim.

15. Claims 54-56 and 60-61 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since the parent Claim 1 requires the exact sequence of SEQ ID NO:1, the breadth intended in Claims 54-56 attempts to broaden the scope of the claims. The encoded protein of Claim 60 is inherent in the scope of Claim 1. And the breadth of "variants" in Claim 61 would broaden the scope as well. This is impermissible in dependent claims. The instant claims will be examined as if they are independent claims.

16. Claim 62 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since sense and antisense are the only options for oligonucleotide orientations, the instant claim removes no breadth of the scope of Claim 12, which is required to further limit the parent claim.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

17. Previous rejection of Claims 1, 7, 10-27, 54-57, and 59-60 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "analogs" is withdrawn by virtue of Applicant's amendment removing this term from the instant claims.

18. Previous rejection of Claims 21-24 under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviation "BAC" is withdrawn by virtue of Applicant's amendment.

19. Previous rejection of Claims 54-56 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "having at least 75% complementary to" is withdrawn by virtue of Applicant's amendment.

Maintained - Claim Rejections - 35 U.S.C. § 112, second paragraph

20. Previous rejection of Claim 16 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "sequence complementary to" is maintained. Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that because Claim 1 refers to a generic nucleic acid molecule, that the nature of SEQ ID NO:1 (which it must comprise) is to be ignored. This is not the case. The Examiner suggests claiming --- ...a nucleic acid molecule having a nucleic acid sequence complementary to the coding sequence as set forth in SEQ ID NO:1--- for clarity.

New - Claim Rejections - 35 U.S.C. § 112, second paragraph

21. Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The antecedent basis of the preamble of Claim 22, as it depends from Claim 21, is unclear. While an adenovirus is part of the Markush group in Claim 21, is Claim 22 intended to limit to said adenovirus (i.e., The vector of Claim 21, wherein the vector is an adenovirus vector that is a replication-deficient adenovirus type 5 expression vector). Clarification is required.

22. Claims 61 and 63 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The term "analog" is unclear as to its metes and bounds. Must the activity be retained by an "analog"? Is so, what activity is that? Must the structure be retained by an "analog"? If so, how much structure? Clarification of the term is required.

By virtue of a similar previous rejection, Applicant has set forth arguments concerning this new rejection. Applicant argues that the term "analog" is defined in the specification on page 13. Therein, the only mention of analogs is with respect to analogs of specific nucleotides, not of an entire nucleotide sequence. Thus, in the instant claims, the above questions apply in the face of this portion of the specification. Applicant also mentions a range of 75-95% identity; however, this limitation cannot be read into the claims even if the Examiner could locate its appearance in the specification.

Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

23. Previous rejection of Claims 1, 7, 10-16, 18-27, 54-56, and 59 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that "the amended claims are thus definite" so the rejection should be withdrawn. First, the Examiner notes that a rejection under first paragraph is not about being definite (that is second paragraph). The relevant rejection is one of written description.

At the heart of the issue of the instant rejection of Claims 1, 7, 10, 11, 16, 18-27, and 59 is that SEQ ID NO:1 is *only a portion* of a full-length gene encoding human p-Hyde protein (186 amino acids); this is clearly evidenced by Applicant's continuation-in-part application (09/562,930) that discloses the full-length human protein of 487 amino acids. In the instant application, rat p-Hyde protein is disclosed as a full-length sequence of 489 amino acids having a

particular function; thus, SEQ ID NO:1 is taught as a *portion* of the human gene homolog. Since all the instant claims are open in scope, they read on at least the entire open reading frame of the human p-Hyde gene. Without specific description (sequence) of such the full-length gene, one of skill in the art would be unable to predict the full-length member of the claimed genus.

With respect to Claims 54-56, an issue here (in addition to the lack of a full-length gene above) is that these claims only require a specific structure in the absence of function. To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. The specification has described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations (i.e., having p-Hyde functionality which is described as the ability to induce cell-death-susceptibility in a cancer cell). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations.

With respect to Claims 12-15, a different issue here is that these claims read on any 15-mer or more that specifically hybridizes to SEQ ID NO:1. This language is totally open allowing for virtually any structure and function so long as the oligonucleotide (which is unlimited in size)

specifically hybridizes. One of skill in the art would be unable to predict members of the claimed genus of such broad scope.

New - Claim Rejections - 35 U.S.C. § 112, first paragraph

24. Claims 60-63 are rejected under 35 U.S.C. § 112, first paragraph, written description. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The issue for Claim 60 is as noted above for Claim 1 (lack of disclosure of the full-length sequence with open claim language). The issue for Claim 62 is as noted above for Claim 12 (any structure, no function). For Claims 61 and 63, no specific structure is limiting due to the unclear definition of "analog". Moreover, the terms "variant" and "mutant" are wholly non-limiting. Thus, these claims lack structure and function as well leaving one of skill in the art unable to predict other members of the claimed genus for the reasons noted above.

Maintained - Claim Rejections - 35 U.S.C. § 101

25. Previous rejection of Claims 1, 7, 10-16, 18-27, 54-56, and 59-60 under 35 U.S.C. § 101 because the claimed invention lacks patentable utility is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that due to similar differential expression and due to sequence similarity, the human sequence disclosed must function as the rat sequence disclosed, which rat sequence was noted as having utility previously by the Examiner. The Examiner disagrees. What is disclosed in the instant application is a *portion* of human p-Hyde. No description is found of what portion of rat p-Hyde

is responsible for the experimentally-determined function of rat p-Hyde, wherein said function, by Applicant's assertion and the Examiner's agreement, would support the utility of the claimed product, human p-Hyde. Thus, it is wholly unknown if this *portion* of human p-Hyde has the rat p-Hyde function. Without evidence that the disclosed *portion* of human p-Hyde has the same function as the rat full-length p-Hyde, the assumption that the disclosed *portion* human p-Hyde has this same functionality is not convincing.

A portion of the previous rejection is repeated below for completeness:

> "The instant claims are drawn to a nucleic acid sequence (p-Hyde gene) encoding a human p-Hyde protein. A p-Hyde protein from rat is characterized in the instant specification; the experiments presented for the rat protein indicate that rat p-Hyde has the ability to induce cell-death-susceptibility in a cancer cell. It can be reasonably assumed that other p-Hyde proteins from other mammals will possess the same, or closely related, activity. The utility of the claimed invention relies on the activity proposed for the rat protein.
>
> The utility of the rat protein and gene cannot be translated into utility for the human protein and gene because is it unclear that the sequences are related. The instant specification discloses cDNA sequences from human (SEQ ID NO:1) and rat (SEQ ID NO:3) encoding a "p-Hyde" protein. These DNA sequences share a region of 84% identity (see attached alignment). The rat protein is 489 amino acids long from a cDNA open reading frame of 1467 base pairs. The human protein is 186 amino acids long from a cDNA open reading frame of 637 base pairs (disclosed SEQ ID NO:1 also contains non-coding regions from 1-78 and from 638-733). It is not convincing that a rat protein of 489 amino acids would have a homolog in human of 186 amino acids, especially one so dissimilar in sequence. Moreover, no structural, domain analysis of the rat sequence has been offered to demonstrate a functional domain that is retained in the shorter human sequence. Thus, without convincing evidence that the disclosed human sequence actually encodes a p-Hyde homolog, the claimed nucleic acid sequences lack a patentable utility.

Claims 61-63 are also rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility as maintained above.

26. Previous rejection of Claims 1, 7, 10-16, 18-27, 54-56, and 59-60 under 35 U.S.C. § 112, first paragraph, enablement, is also maintained for the reasons noted above in the maintaining of the utility rejection.

Claims 61-63 are also rejected under 35 U.S.C. § 112, first paragraph, enablement, because the claimed invention lacks patentable utility as maintained above.

New - Claim Rejections - 35 U.S.C. § 101

27. Claims 12-15 and 62-63 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claims 12 and 63, as written, do not sufficiently distinguish over oligonucleotides as they naturally exist because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206, USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g. by insertion of "isolated" or "purified" as taught by the specification. See M.P.E.P. § 2105.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

28. Previous rejection of Claims 1, 7, 16, and 17 under 35 U.S.C. § 102(b) as being anticipated by Hillier *et al.* is withdrawn by virtue of Applicant's amendment requiring the complete SEQ ID NO:1 in the claims, which is not anticipated by Hillier *et al.* who teaches only a fragment of SEQ ID NO:1.

29. Previous rejection of Claims 1, 7, 10, 11, 16-21, 25-27, 54-56 and 59 under 35 U.S.C. § 102(b) as being anticipated by Talerman *et al.* is withdrawn by virtue of Applicant's amendment requiring the complete SEQ ID NO:1 in the claims, which is not anticipated by Talerman *et al.* who teaches only sequence related to SEQ ID NO:1 outside the % identity limitations of even Claim 54.

Maintained - Claim Rejections - 35 U.S.C. § 102

30. Previous rejection of Claims 12 and 13 under 35 U.S.C. § 102(b) as being anticipated by Hillier *et al.* is maintained. Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that the prior art must teach the p-Hyde coding sequence to anticipate Claim 12; the Examiner disagrees. The prior art need only teach a sequence that will hybridize to SEQ ID NO:1 and be at least 15 nucleotides; Hillier *et al.* meet these requirements.

31. Previous rejection of Claims 12-15 under 35 U.S.C. § 102(b) as being anticipated by Talerman *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicant argues that Talerman *et al.* fails to teach that their DNA would specifically hybridize to SEQ ID NO:1; however, this feature is inherent in the DNA of Talerman *et al.* due to the sequence similarity. Applicant argues that the prior art must teach the p-Hyde coding sequence to anticipate Claim 12; the Examiner disagrees. The prior art need only teach a sequence that will hybridize to SEQ ID NO:1 and be at least 15 nucleotides; Talerman *et al.* meet these requirements.

New - Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

32. Claims 62-63 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hillier *et al.* or Talerman *et al.* for the reasons noted above in the maintained rejections of Claims 12-15.

33. Claims 12-15, 54, 55, and 61-63 are rejected under 35 U.S.C. § 102(e) as being anticipated by Ni *et al.* (USPAP 2002/0064818). The instant claims are drawn to nucleotide sequences that will hybridize to SEQ ID NO:1, sharing at least 85% identity, and being linked to detectable, radioactive markers.

Ni *et al.* teaches 1038 bp DNA of SEQ ID NO:17 that is a fragment of Applicant's SEQ ID NO:1 having an overall sequence identity of greater than 90% (see attached alignment). Ni *et al.* also teach labeling the DNA's of their invention (see paragraph 790).

The Examiner notes that this sequence taught by Ni *et al.* is granted priority to the earlier filing date of September 3, 1999 having been disclosed in the provisional application 60/152,315.

Summary of Pending Issues

34. The following is a summary of the issues pending in the instant application; each item must be addressed in response to the instant Office action:

a) The specification stands objected to for containing confusing reference materials.
b) The Abstract stands objected to for being incomplete.
c) The specification stands objected to for its unclear reference to SEQ ID NO:7 as amended into page 83.
d) Claim 1 stands objected to for having improper language.
e) Claim 7, 26, 54-56 and 60-62 stand objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
f) Claim 16 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "sequence complementary to".
g) Claim 22 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of the preamble.
h) Claims 61 and 63 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "analog".
i) Claims 1, 7, 10-16, 18-27, 54-56, and 59-63 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
j) Claims 1, 7, 10-16, 18-27, 54-56, and 59-63 stand rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.
k) Claims 1, 7, 10-16, 18-27, 54-56, and 59-63 under 35 U.S.C. § 112, first paragraph, enablement.
l) Claims 12-15 and 62-63 stand rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.
m) Claims 12, 13 and 62-63 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hillier *et al.*
n) Claims 12-15 and 62-63 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Talerman *et al.*
o) Claims 12-15, 54, 55, and 61-63 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Ni *et al.* (USPAP 2002/0064818).

Reiterated - Examiner's Comment

35. For clarity of the record, the Examiner requests an explanation for the omission of Chiang Wang as an inventor of the claimed invention. Chiang Wang appears, with the other inventors, as an inventor in the WIPO document, WO 2000 071564 A2. Comment concerning

the inventorship of the instant application, with respect to Chiang Wang, is required in response to the instant Office action. **Failure to address this issue will result in the reply being held non-responsive.**

36. As previously noted, the Examiner suggests the inclusion of the 489 amino acid rat protein deduced from the 1467 base pair cDNA in the sequence listing. The Examiner previously suggested such an inclusion; Applicants neither added the sequence nor commented on why it was not necessary. As previously noted, often times, a disclosed protein can be overlooked because only its encoding DNA sequence is searchable (in a sequence listing). For completeness, the inclusion of the rat protein sequence is recommended. The rat full-length protein sequence would not be considered new matter if it is *exactly* encoded by the cDNA disclosed in SEQ ID NO:3. An alignment of the coding DNA and the added amino acid should be included to clearly show support and the lack of new matter.

Conclusion

37. Claims 1, 7, 10-16, 18-27, 54-56, and 59-63 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kathleen M Kerr
Examiner
Art Unit 1652

July 22, 2004

ALIGNMENT

US-09-789-561-17
; Sequence 17, Application US/09789561
; Patent No. US20020064818A1
; GENERAL INFORMATION:
; APPLICANT: Ni et al.
; TITLE OF INVENTION: 52 Human secreted proteins
; FILE REFERENCE: PZ043P1
; CURRENT APPLICATION NUMBER: US/09/789,561
; CURRENT FILING DATE: 2001-02-22
; PRIOR APPLICATION NUMBER: PCT/US00/24008
; PRIOR FILING DATE: 2000-08-31
; PRIOR APPLICATION NUMBER: 60/152,317
; PRIOR FILING DATE: 1999-09-03
; PRIOR APPLICATION NUMBER: 60/152,315
; PRIOR FILING DATE: 1999-09-03
; NUMBER OF SEQ ID NOS: 194
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO 17
; LENGTH: 1038
; TYPE: DNA
; ORGANISM: Homo sapiens
; FEATURE:
; NAME/KEY: SITE
; LOCATION: (963)
; OTHER INFORMATION: n equals a,t,g, or c
; NAME/KEY: SITE
; LOCATION: (1025)
; OTHER INFORMATION: n equals a,t,g, or c
US-09-789-561-17

Query Match 90.4%; Score 662.6; DB 9; Length 1038;
Best Local Similarity 99.0%; Pred. No. 1e-180;
Matches 676; Conservative 1; Mismatches 5; Indels 1; Gaps 1;

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Qy         39 CAACAAGAGCCACCTCTGGGTGGAGGAGGAGGTCTGGCGGATGGAGATCTACCTCTCCCT 98
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Db          2 CAACAAGAGCCACCTCTGGGTGRAGGAGGAGGTCTGGCGGATGGAGATCTACCTCTCCCT 61

Qy         99 GGGAGTGCTGGCCCTCGGCACGTTGTCCCTGCTGGCCGTGACCTCACTGCCGTCCATTGC 158
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         62 GGGAGTGCTGGCCCTCGGCACGTTGTCCCTGCTGGCCGTGACCTCACTGCCGTCCATTGC 121

Qy        159 AAACTCGCTCAACTGGAGGGAGTTCAGCTTCGTTCAGTCCTCACTGGGCTTTGTGGCCCT 218
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        122 AAACTCGCTCAACTGGAGGGAGTTCAGCTTCGTTCAGTCCTCACTGGGCTTTGTGGCCCT 181

Qy        219 CGTGCTGAGCACACTGCACACGCTCACCTACGGCTGGACCCGCGCCTTCGAAGAGA-CCG 277
              |||||||||||||||||||||||||||||||||||||||||||||||||||| |||| |||
Db        182 CGTGCTGAGCACACTGCACACGCTCACCTACGGCTGGACCCGCGCCTTCGAGGAGAGCCG 241

Qy        278 CTACAAGTTGTACCTGCCTCCCACCTTCACGCTCACGCTGCTGGTGCCCTGCGTCGTCAT 337
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        242 CTACAAGTTCTACCTGCCTCCCACCTTCACGCTCACGCTGCTGGTGCCCTGCGTCGTCAT 301

Qy        338 CCTGGCCAAAGCCCTGTTTCTCCTGCCCTGCATCAGCCGCAGACTCCCCAGGATCCGGAG 397
              |||||||||||||||||||||||||||||||||||||||||||||| ||||||||||||
Db        302 CCTGGCCAAAGCCCTGTTTCTCCTGCCCTGCATCAGCCGCAGACTCGCCAGGATCCGGAG 361
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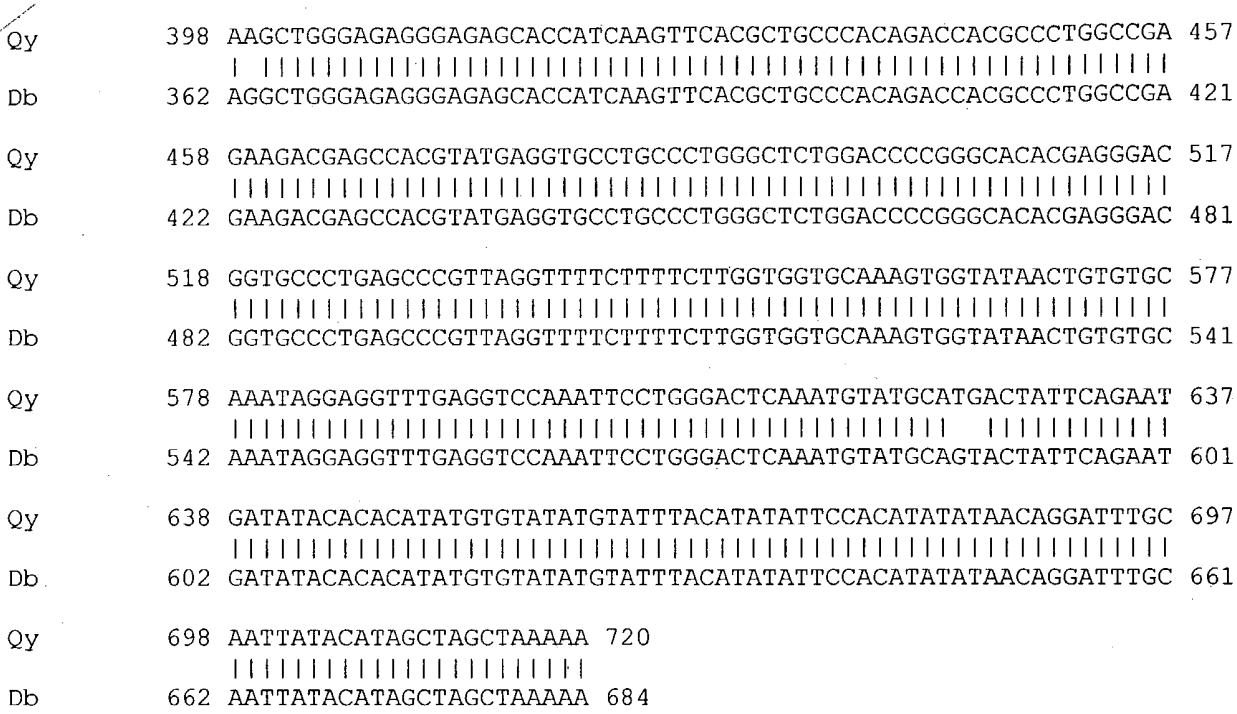
Qy 398 AAGCTGGGAGAGGGAGAGCACCATCAAGTTCACGCTGCCCACAGACCACGCCCTGGCCGA 457
Db 362 AGGCTGGGAGAGGGAGAGCACCATCAAGTTCACGCTGCCCACAGACCACGCCCTGGCCGA 421
Qy 458 GAAGACGAGCCACGTATGAGGTGCCTGCCCTGGGCTCTGGACCCCGGGCACACGAGGGAC 517
Db 422 GAAGACGAGCCACGTATGAGGTGCCTGCCCTGGGCTCTGGACCCCGGGCACACGAGGGAC 481
Qy 518 GGTGCCCTGAGCCCGTTAGGTTTTCTTTTCTTGGTGGTGCAAAGTGGTATAACTGTGTGC 577
Db 482 GGTGCCCTGAGCCCGTTAGGTTTTCTTTTCTTGGTGGTGCAAAGTGGTATAACTGTGTGC 541
Qy 578 AAATAGGAGGTTTGAGGTCCAAATTCCTGGGACTCAAATGTATGCATGACTATTCAGAAT 637
Db 542 AAATAGGAGGTTTGAGGTCCAAATTCCTGGGACTCAAATGTATGCAGTACTATTCAGAAT 601
Qy 638 GATATACACACATATGTGTATATGTATTTACATATATTCCACATATATAACAGGATTTGC 697
Db 602 GATATACACACATATGTGTATATGTATTTACATATATTCCACATATATAACAGGATTTGC 661
Qy 698 AATTATACATAGCTAGCTAAAAA 720
Db 662 AATTATACATAGCTAGCTAAAAA 684